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7590 03/22/2007 Thomas H. Close			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/679,711	CHEN ET AL.			
Office Action Summary	Examiner	Art Unit			
	Jayesh A. Patel	2624			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  ill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	L. ely filed the mailing date of this communication. C (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 07 Ma	arch 2007.				
2a) ☑ This action is FINAL. 2b) ☐ This	action is non-final.				
3) Since this application is in condition for allowar	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.			
Disposition of Claims					
4) ☐ Claim(s) 1-23 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-23 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or					
Application Papers		-			
<ul> <li>9) The specification is objected to by the Examine 10) The drawing(s) filed on <u>06 October 2003</u> is/are: Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction. 11) The oath or declaration is objected to by the Examine. </li> </ul>	a)⊠ accepted or b)□ objected drawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te			

Application/Control Number: 10/679,711
AVE Unit: 2624 Response to Armin

# Response to Arguments

1. Applicant's arguments filed 02/23/07 have been entered and made of record.

Applicant's arguments with respect to claims 1 and 12 have been considered but are moot in view of the new ground(s) of rejection.

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Adler et al. (US 20020177779 A1) hereafter Adler.

- 2. Regarding Claim 1. Adler discloses a digital image processing method in (Figs 1, 3 and 4) for real-time automatic abnormality detection of in vivo images,
- comprising the steps of:
- a) forming an examination bundlette of a patient that includes real-time captured

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in vivo images and image specific metadata relating to only a portion of a gastrointestinal tract at a specific time on (Page 2 Para 0020 and 0021). The Capsule takes the images of the GI tract, forms an examination bundlette of the in-vivo images with the metadata (data about images tagged with the images) and sends it to the processor for analysis.

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- b) real-time image processing of image packets within the examination bundlette at (Page 2 Para 0021 Lines 11-12) by Data processor 14 in Fig 1.
- c) automatically detecting and analyzing one or more abnormalities in the examination bundlette's real-time captured images using image processing algorithms (Data processor 14 in Fig 1) in cooperation with predetermined criteria for the patient at (Page 2 Para 0022, 0023 and Fig 4); and
- d) signaling an alarm provided that the one or more abnormalities in the examination bundlette have been automatically detected on (Page 3 Para 0036 and 0037). The color video showing the presence of the blood as a graph or table indicating the levels and /or threshold values and the display results incorporating position indicator will act as an alarm for the physician in dealing with the problem.
- 3. Regarding Claim 12, Adler discloses a digital image processing system in (Fig 1,3 and 4) for real-time automatic abnormality detection of in vivo images, comprising:
- a) means for forming an examination bundlette of a patient that includes real-time

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captured in vivo images and image specific metadata relating to only a portion of a gastrointestinal tract at a specific time in (Fig 1 Element 40,12 and 19);

- b) means for real-time image processing of image packets within the examination bundlette in (Fig 1 Elements 40,12,14 and 19);
- c) means for automatically detecting and analyzing (Element 22 Fig 3) one or more abnormalities in the examination bundlette's real-time captured images using image processing\_algorithms in cooperation with based on predetermined criteria for the patient in (Fig 1 Elements 12,19,14 and Fig 4 algorithm); and d) means for automatically signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected by (Data processor 14 and image monitor 18). The color video showing the presence of the blood as a graph or table indicating the levels and /or threshold values and the display results incorporating position indicator will act as an alarm for the physician in dealing with the problem at (Page 3 Para 0036 and 0037).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1,7,9-12,18,20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron (US 6950690) hereafter Meron in view of Adler.

- 4. Regarding Claim 1, Meron discloses a digital image processing method in (Figs 1 and 6) for real-time automatic abnormality detection of in vivo images, comprising the steps of:
- a) forming an examination bundlette of a patient that includes real-time captured in vivo images and image specific metadata relating to only a portion of a gastrointestinal tract at a specific time in (Col 6 Lines 19- 34). The Capsule takes the images of the GI tract, forms an examination bundlette of the in-vivo images with the metadata (data about images tagged with the images) and sends it to the processor for analysis. Meron however does not disclose and is silent about the elements b),c) and d).

Adler discloses **b**) real-time image processing of image packets within the examination bundlette at (Page 2 Para 0021 Lines 11-12) by Data processor 14 in Fig 1. **c**) automatically detecting and analyzing one or more abnormalities in the examination bundlette's real-time captured images using image processing algorithms (Data processor 14 in Fig 1) in cooperation with predetermined criteria for the patient at (Page 2 Para 0022, 0023 and Fig 4); and d) signaling an alarm provided that the one or more abnormalities in the examination bundlette have been automatically detected on (Page 3 Para 0036 and 0037). The color video showing the presence of the blood as a graph or table indicating

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the levels and /or threshold values and the display results incorporating position indicator will act as **an alarm** for the physician in dealing with the problem. The image data can be processed in **real time** by the data processor 14 at (**Page 2**) **Para 0021 Lines 11,12**). Both Meron and Adler are from the same field of endeavor and are analogous art; therefore it would have been obvious for one of ordinary skill in the art to use the teachings of Adler for real time processing of Images obtained by the method and system of Meron.

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- 5. Regarding Claim 12, Meron discloses a digital image processing system in (Fig 1 and 6) for real-time automatic abnormality detection of in vivo images, comprising:
- a) means for forming an examination bundlette of a patient that includes real-time captured in vivo images and image specific metadata relating to only a portion of a gastrointestinal tract at a specific time in (Fig 6 Element 60 and Fig 1 Elements 10,12,14 and 19). A capsule 60 is captures real time in-vivo images and forms an examination bundlette. Meron however, does not specifically and is silent about real time image processing and automatically detecting abnormalities using algorithms.

Adler discloses **b)** means for real-time image processing of image packets within the examination bundlette in (**Fig 1 Elements 40,12,14 and 19**); **c)** means for automatically detecting and analyzing (**Element 22 Fig 3**) one or more abnormalities in the examination bundlette's real-time captured images

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using image processing algorithms in cooperation with based on predetermined criteria for the patient in (Fig 1 Elements 12,19,14 and Fig 4 algorithm); and d) means for automatically signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected by (Data processor 14 and image monitor 18). The color video showing the presence of the blood as a graph or table indicating the levels and /or threshold values and the display results incorporating position indicator will act as an alarm for the physician in dealing with the problem at (Page 3 Para 0036 and 0037). Meron discloses the sensing of blood in the GI tract through sensor 49 at (Col 4 Lines 65-67). Adler discloses the generating a probability indication of the presence of blood based on comparison of the color content of the received images and at least one-reference values at (Page 1 Para 0010 and 0011). The image data can be processed in real time by the data processor 14 at (Page 2 Para 0021 Lines 11,12). Both Meron and Adler are from the same field of endeavor and are analogous art; therefore it would have been obvious for one of ordinary skill in the art to use the teachings of Adler for real time processing of Images obtained by the method and system of Meron.

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**6.** Regarding Claim 7, Meron and Adler disclose all the limitations of Claim 1. Meron further discloses, The method claimed in claim 1, wherein the step of automatically detecting the one or more abnormalities includes the steps of: c1) detecting parameters that are substantially different from a given geometric

template of physical data as identified in the in vivo images at (Col 4, Lines 65-67). The temp, pressure and pH sensors detect the non-physical data.

- 7. Regarding Claim 9, Adler and Meron discloses all the limitations of claims 1 and 7. The phrase "geometric template formed by training a template according to the predetermined criteria" carries no weight since the specific method of producing the template is not part of the method claimed.
- 8. Regarding Claim 10, Adler and Meron disclose all the limitations of claim 1. Meron further discloses, the method claimed in claim 1, wherein the step of signaling the alarm includes the steps of: d1) providing a communication channel to a remote site; and d2) sending the alarm to the remote site at (Col 6, Lines 24-30).
- **9.** Regarding Claim 11, Meron and Adler disclose all the limitations of claim 1. Meron further discloses, the method claimed in claim 1, wherein the step of signaling the alarm includes the steps of: d1) providing a communication channel to a local site; and d2) sending the alarm to the local site at **(Col 1, Lines48-67)**.
- **10.** Regarding Claim 18, Meron and Adler disclose all the limitations of Claim 12.

  Meron further discloses means for detecting parameters that are substantially

different from a given geometric template of physical data as identified in the in vivo images at (Col 4, Lines 65-67).

- 11. Regarding Claim 20, Meron and Adler disclose all the limitations of claims 12 and 18. The phrase "geometric template formed by training a template according to the predetermined criteria" carries no weight for the reasons stated above with respect to Claim 9.
- **12.** Regarding Claim 21, Meron and Adler disclose all the limitations of Claim 12. Meron further discloses, the system claimed in claim 12, wherein the means for signaling the alarm further comprises: d1) means for providing a communication channel to a remote site; and d2) means for sending the alarm to the remote site at **(Col 6, Lines 19-34)**.
- **13.** Regarding Claim 22, Meron and Adler disclose all the limitations of Claim 12. Meron further discloses, the means for signaling the alarm further comprises: d1) means for providing a communication channel to a local site; and d2) means for sending the alarm to the local site at **(Col 1, Lines48-67)**.
- 14. Regarding Claim 23, Meron discloses, An in vivo camera for employing real-time automatic abnormality detection of in vivo images, comprising: a) A capsule60 for forming an examination bundlette of a patient that includes real-time

captured in vivo images at (Col 6, Lines 4-6). b) A data processor 66 for processing the examination bundlette at (Col 6, Lines 35-38).

Meron however does not disclose and is silent about c) Means for automatically detecting one or more abnormalities in the examination bundlette based on predetermined criteria for the patient; and d) means for signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected.

Adler discloses c) Means for automatically detecting one or more abnormalities in the examination bundlette based on predetermined criteria for the patient at (Fig 1 Elements 12,19,14 and Fig 4 Algorithm); and d) means for signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected at (Data processor 14 and image monitor 18). The color video showing the presence of the blood as a graph or table indicating the levels and /or threshold values and the display results incorporating position indicator will act as an alarm for the physician in dealing with the problem at (Page 3 Para 0036 and 0037). Meron discloses the sensing of blood in the GI tract through sensor 49 at (Col 4 Lines 65-67). Adler discloses the generating a probability indication of the presence of blood based on comparison of the color content of the received images and at least onereference values at (Page 1 Para 0010 and 0011). The image data can be processed in real time by the data processor 14 at (Page 2 Para 0021 Lines 11,12). Both Meron and Adler are from the same field of endeavor and are

analogous art; therefore it would have been obvious for one of ordinary skill in the art to use the teachings of Adler for real time processing of Images obtained by the method and system of Meron.

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler and in further view of Wortmann et al. (US 2003/0149680) hereafter Wortmann.

**15.** Regarding Claim 2, Meron and Adler disclose all the limitations of Claim 1. Meron also discloses about forming an image packet of the real-time captured in vivo images of the patient in **(Col 6, Lines 19-24)**. However Meron does not disclose forming patient's metadata and combining the image packet with the patient's metadata.

Wortmann discloses combining patient metadata with image data on Page 1 Para 0003 and 0005. The DICOM object format contains a header and image data. The header contains information such as patient's name, type of medical procedure or scan etc. The image data contains the pixel information. Wortmann uses DICOM (Digital Imaging and Communications in Medicine) protocol for communicating between two devices in the communications network. In such a network the medical staff can retrieve images by using Metadata information. The communication is configured for easy extraction of the patient data from the image database and helps in better media maintenance. The use of DICOM also

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allows data to be transformed into different form when transported. This limits the consumption of memory. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to use the DICOM protocol header as taught by Wortmann in the method and apparatus of capturing images of a lumen as taught by Meron and Adler.

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**16.** Regarding Claim 13, Meron anticipates all the limitations of Claim 12. Meron also discloses about forming an image packet of the real-time captured in vivo images of the patient in **(Col 6, Lines 19-24)**. However Meron does not disclose forming patient's metadata and combining the image packet with the patient's metadata.

Wortmann discloses combining patient metadata with image data on Page 1 Para 0003 and 0005. The DICOM object format contains a header and image data. The header contains information such as patient's name, type of medical procedure or scan etc. The image data contains the pixel information. Wortmann uses DICOM (Digital Imaging and Communications in Medicine) protocol for communicating between two devices in the communications network. In such a network the medical staff can retrieve images by using Metadata information. The communication is configured for easy extraction of the patient data from the image database and helps in better media maintenance. The use of DICOM also allows data to be transformed into different form when transported. This limits the consumption of memory. Therefore, it would have been obvious to one of

ordinary skill in the art, at the time the invention was made to use the DICOM protocol header as taught by Wortmann in the method and apparatus of capturing images of a lumen as taught by Meron.

Claims 6,8,17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler and in further view of Zhang et al. (US 6181810) hereafter Zhang.

17. Regarding Claim 6, Meron and Adler disclose all the limitations of Claim 1.

Adler discloses detecting colorimetric abnormalities by processing pixels on

(Page 2 Para 0023), however does not disclose detecting the abnormality by threshold value of the pixels.

Zhang discloses detecting abnormalities by selecting the pixels that exceed the predetermined value at (Col 2, Lines 57-61). The pixel values above the threshold limit will have a binary value 1 and the pixel values below the threshold will have a binary value 0. This approach can enhance the edge between blood and tissue making error free diagnosis. Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made to incorporate the image enhancing techniques as taught by Zhang for detecting abnormality (presence of blood) in the device delivery at the pathology location used by Meron and Adler.

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**18.** Regarding Claim 8, see explanation of claim 6. Zhang further discloses the given threshold is based on the statistical data according to the predetermined criteria in (Col 2, Lines 59-61).

19. Regarding Claim 17, Meron and Adler disclose all the limitations of claim 12. Adler discloses processing pixels for detecting abnormalities on (Page 2 Para 0023), however Adler and Meron do not disclose detecting the abnormality by threshold value of the pixels.

Zhang discloses detecting abnormalities by selecting the pixels that exceed the predetermined value at (Col 2, Lines 57-61). The pixel values above the threshold limit will have a binary value 1 and the pixel values below the threshold will have a binary value 0. This approach can enhance the edge between blood and tissue making error free diagnosis. Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made to incorporate the image enhancing techniques as taught by Zhang for detecting abnormality (presence of blood) in the method used by Meron.

20. Regarding Claim 19, see explanation of claim 17. Zhang further discloses a threshold based on statistical data according to the predetermined criteria in (Col 2, Lines 59-61).

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler and in view of Christensen et al. (US 6243502) hereafter Christensen.

21. Regarding Claim 3, Meron and Adler anticipates all the limitations of the claim 1. Meron however does not disclose the steps of processing the examination bundlette, that includes the steps of: b1) separating the in vivo images from the examination bundlette; and b2) processing the in vivo images according to selected image processing methods.

Christensen discloses separating the header information from the image – description included in the original file prior to processing of the image by an editing package at (Col 2, Lines 64-67 and Col 3, Lines 1-15). There are lots of image editing techniques that deletes the image description and the color interpretation of the image's pixel. It is important to save the original information. The image header contains the original information regarding an image.

Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made to include the extraction of image description/quality information prior to processing as taught by Christensen in the method performed by Meron and Adler (at Data processor 66).

Claim 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler, Christensen and in further view of Qian (US 6332033) hereafter Qian.

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22. Regarding Claim 4 the claimed limitation of performing noise filtering is an extremely conventional process in all types of image processing. It is so common to perform noise filtering to achieve best results in image processing. Also Meron and Christensen discloses all the limitations of Claims 1 and 3, except the color space conversion of images from RGB space to generalized RGB space.

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Qian discloses the color space conversion of images from RGB to (r, g) at (Col 3, Lines 37-65 and Col 4,Lines 1-13). The color blue is redundant after the process of normalization. Also the chances of false detection of the pixels are greatly reduced by normalization process. The purpose of the conversion is to 1) Distinguish skin color from other objects of the image and 2) To detect skin tones irrespective of color of the person's skin which differ from person to person and differs for the same person under different lighting conditions. Therefore it would have been obvious for one of ordinary skill in the art, at the time the invention was made to incorporate the conversion/filter as taught by Qian in the methods of delivery and Image capture as taught by Meron and image quality maintenance as taught by Christensen for the above stated reasons.

23. Regarding Claim 5, see explanation of claim 4.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler in view of Christensen.

selected image processing methods.

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24. Regarding Claim 14, Meron and Adler disclose all the limitations of the claim 12. Meron however does not disclose the steps of processing the examination bundlette, that includes the steps of: b1) separating the in vivo images from the examination bundlette; and b2) processing the in vivo images according to

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Christensen discloses separating the header information from the image — description included in the original file prior to processing of the image by an editing package at (Col 2, Lines 64-67 and Col 3, Lines 1-15). There are lots of image editing techniques that deletes the image description and the color interpretation of the image's pixel. It is important to save the original information. The image header contains the original information regarding an image.

Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made to include the extraction of image description/quality information prior to processing as taught by Christensen in the method performed by Meron and Adler.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron, Adler, Christensen and in further view of Qian.

**25.** Regarding Claims 15 the claimed limitation of performing noise filtering is an extremely conventional process in all types of image processing. It is so common

to perform noise filtering to achieve best results in image processing. Also Meron and Christensen discloses all the limitations of Claims 12 and 14, except the color space conversion of images from RGB space to generalized RGB space.

Qian discloses the color space conversion of images from RGB to (r, g) at (Col 3, Lines 37-65 and Col 4,Lines 1-13). The color blue is redundant after the process of normalization. Also the chances of false detection of the pixels are greatly reduced by normalization process. The purpose of the conversion is to 1) Distinguish skin color from other objects of the image and 2) To detect skin tones irrespective of color of the person's skin which differ from person to person and differs for the same person under different lighting conditions. Therefore it would have been obvious for one of ordinary skill in the art, at the time the invention was made to incorporate the conversion/filter as taught by Qian in the methods of delivery and Image capture as taught by Meron and image quality maintenance as taught by Christensen for the above stated reasons.

**26.** Regarding Claim 16, see the explanation of claim 15.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jayesh A. Patel whose telephone number is 571-270-1227. The examiner can normally be reached on M-F 7.00am to 4.30 pm (5-4-9). If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Jingge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jayesh Patel 03/19/07

TP

PERVISORY PARENT EXAMINER